

Congress of the United States
Washington, DC 20515

July 26, 2019

The Honorable Norman E. Sharpless
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless,

In recent years advances in animal genetics have provided significant breakthroughs that can help to address some of society's most difficult challenges. These technologies can treat and protect animals from illness; limit the transmission of dangerous diseases, like African swine fever or avian influenza; curb the use of antibiotics in agriculture; address hunger and insect-borne disease in developing nations; improve animal welfare; among many other benefits. However, we are concerned that the current regulatory approach may unintentionally set the United States up to limit domestic access to these innovations by farmers, consumers, and public health officials. Equally concerning, this approach is driving research and first access to these advances into the hands of foreign competitors. U.S.-based companies are already turning to foreign markets for development and marketing of animal innovations. We encourage you to work with other relevant agencies and stakeholders to develop a revised regulatory approach for animal biotechnology that is science and risk-based, provides a viable pathway to market, and ensures the safety of these products for humans, animals, and our environment.

Under the Food, Drug & Cosmetic Act, the U.S. Food & Drug Administration (FDA) currently regulates the DNA of all intentionally altered animals and all of their offspring as an "animal drug" – even if alterations could have happened naturally or through conventional breeding. This regulatory process, which can take years, if not decades to complete, also carries enormous regulatory costs. This burden is deterring many academics and developers from conducting research and will likely consolidate the industry to only the largest companies. In fact, in the agency's nearly 25 years of regulating these animals, only one animal intended for food has ever been approved, delaying many important innovations.

We are worried that there may be many unintended consequences with FDA's approach as well. For example, many U.S.-produced animals are currently bound for international commerce. Suggesting that U.S.-raised animals contain a "drug" invites foreign competitors to impose non-tariff trade barriers on U.S. goods. Foreign governments are also implementing their own regulatory systems to attract U.S. researchers who feel stymied. Argentina recently completed review of a gene edited animal in less than a year – an effort that may take a decade under FDA's existing approach. Brazil, Canada, China, and others are undergoing similar efforts. To maintain competitiveness, it is critical that the U.S. reconsider its current approach.

While we think a robust conversation should be had on the best way to provide transparency to consumers and users on the nature of these animals, that discussion will be moot if our nation's regulatory system prevents these animals from coming to market. We again urge you to work

with other relevant agencies and stakeholder communities to develop a more appropriate, workable approach that will provide sufficient safeguards, while allowing U.S. farmers, consumers, and public health officials access to animal innovations.

Sincerely,



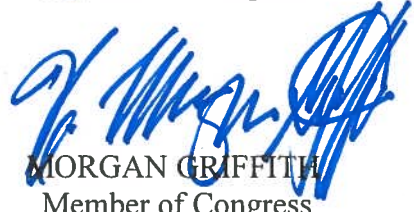
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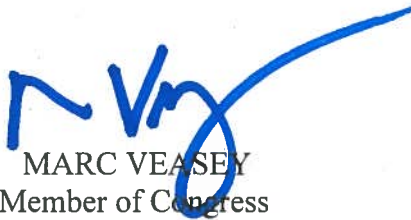
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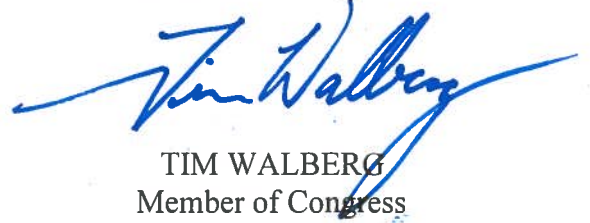
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